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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,638	02/18/2004	Renwen Zhang	08702.0068-01000	9082
22852	7590	11/18/2005	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/779,638	Applicant(s) ZHANG ET AL	
	Examiner Hope A. Robinson	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 15-37 is/are pending in the application.
- 4a) Of the above claim(s) 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-23 and 29-37 is/are rejected.
- 7) ☒ Claim(s) 24-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/28/04: 3/28/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

2. Applicant's election without traverse of Group IV (claims 20-37) is acknowledged.

Claims 1-14 have been canceled. Claims 15-37 have been added. Claims 15-37 are pending. Claims 20-37 are under examination. Claims 15-19 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

3. The Amendments filed on February 18, 2003, June 3, 2004 and June 15, 2005 have been received and entered.

### ***Abstract***

4. The abstract is objected to because of the following informalities:

The abstract is objected to because the following appears in the last line, "The method results in the regeneration of functional repair of articular cartilage tissue". This statement can be interpreted as functional repair of articular cartilage tissue is regenerated or since the method is to regeneration of articular cartilage, it can be interpreted as the method results in regeneration and repair of articular cartilage which

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would mean that applicant has a typographical error in the abstract. Clarification is required.

***Information Disclosure Statement***

5. The Information Disclosure Statements filed on June 28, 2004 and March 28, 2005 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

***Claim Objection***

6. Claims 24-28 are objected to because of the following informalities:

Claims 24-28 are objected to because the claims depend from a rejected based claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 29-35 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 29 is indefinite for the recitation of "wherein said composition is administered directly to the osteochondral graft or to the site in need of tissue repair", because the first part of the claim recites, "a method for regeneration of articular cartilage comprising administering to an area in need of regeneration of said articular cartilage an osteochondral graft". Thus, the osteochondral graft is administered having the composition applied thereto and not the composition directly to the site in need of tissue repair. The dependent claims hereto are also included in this rejection because they do not rectify the deficiencies.

Claim 31 is indefinite for the recitation of an improper Markush group. It is suggested that the claim is amended to recite "selected from the group consisting of the hip and the knee". The dependent claims hereto are also included in this rejection because they do not rectify the deficiencies.

### ***Basis For NonStatutory Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 20-23, 29 and 31-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-10 and 12-13 of U.S. Patent No. 6,727,224. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claims are directed to a method for regeneration of articular cartilage comprising administering to an area in need of regeneration of articular cartilage an osteochondral graft having applied thereto a composition consisting essentially of an amount of a heterodimer effective for the regeneration of

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articular cartilage, wherein the heterodimer comprises one purified bone morphogenetic protein (BMP) and one protein which induces the formation of tendon or ligament tissue. The patented claims are directed to a method for regeneration of articular cartilage comprising administering to an area in need of regeneration of articular cartilage an osteochondral graft having applied thereto a composition consisting essentially of an amount of at least one purified bone morphogenetic protein (BMP) effective for the regeneration of said articular cartilage. The dependent claims in the patent and instant application are both drawn to BMP-2, BMP-12, BMP-13, members of the BMP-12 subfamily and MP52. The two sets of claims differ as the instant application claim recites "a heterodimer comprising a BMP" and the instant claim recites "carriers for the claimed composition". However, the specification of the patent disclose that the BMP of the invention may be heterodimeric with other BMPs (see column 2-3) and as the patented claims recite a composition, the instant claims are obvious. The art recognizes that a carrier could simply be water. Therefore, as the patented composition is administered to an area in need of cartilage regeneration, absent evidence to the contrary a carrier is used as such is necessary for delivery of the composition. Furthermore, claim 29 of the instant application is obvious, although the claim recites direct administration. Note that the patented claims recite administration to an area in need of regeneration of cartilage, thus, direct administration is achieved. With regard to claim 31 of the instant application, the selection of hip or knee is obvious (see also claims 32-37), because they are weight-bearing joints that would obviously be vulnerable to cartilage loss and require repair.

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Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the same material. One of ordinary skill in the art would be motivated to modify the patented claims to recite, for example "heterodimer" because the patent disclose that it is a part of the invention. Thus, the copending claims are an obvious variation of the instant application claim, therefore prima facie obvious.

This is a obvious-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS *HR*

Patent Examiner *11/10/05*

**HOPE ROBINSON  
PATENT EXAMINER**